

**IN THE CLAIMS**

The claims pending in the application are reproduced below for the convenience of the Examiner.

Please cancel claims 44-47 without prejudice.

1. (Original) A device for measuring a body-tissue water content metric as a fraction of the fat-free tissue content of a patient using optical spectrophotometry, comprising:
  - a probe housing configured to be placed proximal to a tissue location which is being monitored;
  - light emission optics connected to said housing and configured to direct radiation at said tissue location;
  - light detection optics connected to said housing and configured to receive radiation from said tissue location; and
  - a processing device configured to process radiation from said light emission optics and said light detection optics to compute said metric wherein said metric comprises a ratio of the water content of a portion of patient's tissue in relation to the lean or fat-free content of a portion of patient's tissue.
2. (Original) The device of claim 1 wherein said body-tissue water content metric is computed as a fraction of bone-free-fat-free tissue content.
3. (Original) The device of claim 1 further comprising a display device connected to said probe housing and configured to display said water content.



4. (Original) The device of claim 1 wherein said light emission optics and said light detection optics are spaced between 1 and 5 mm from one another at said tissue location.
5. (Original) The device of claim 1, wherein said body-tissue metric is monitored intermittently.
6. (Original) The device of claim 1 wherein said body-tissue metric is monitored continuously.
7. (Original) The probe housing of the device of claim 1 further comprising a spring-loaded probe configured to automatically activate a display device connected to said probe housing when said spring-loaded probe is pressed against and near a tissue location which is being monitored.
8. (Original) The probe housing of the device of claim 1 further comprising a pressure transducer to measure the compressibility of tissue for deriving an index of a fraction of free water within said tissue.
9. (Original) The probe housing of the device of claim 1 further comprising a mechanism for mechanically inducing a pulse within said tissue location to permit measurements related to the differences between an intravascular fluid volume and an extravascular fluid volume fractions under weak-pulse conditions.
10. (Original) The probe housing of the device of claim 1 further comprising a mechanism for mechanically minimizing the pressure at said tissue location to permit measurements related to the unperturbed fluid volume fraction in the tissue.



11. (Original) The probe housing of the device of claim 1 further comprising a mechanism for mechanically inducing pressure at said tissue location to permit measurement of the extravascular fluid fraction in the absence of the intravascular fluid fraction.
12. (Original) The probe housing of the device of claim 1 further comprising a mechanism for mechanically varying pressure at said tissue location to permit measurement of both the intravascular and extravascular water fraction.
13. (Original) The device of claim 1, wherein said light emission optics are tuned to emit radiation at a plurality of narrow spectral wavelengths chosen so that the biological compound of interest will absorb light at said plurality of narrow spectral wavelengths and so that absorption by interfering species will be at a minimum, where a minimum absorption is an absorption by an interfering species which is less than 10% of the absorption of the biological compound of interest.
14. (Original) The device of claim 1, wherein said light emission optics are tuned to emit radiation at a plurality of narrow spectral wavelengths chosen to be preferentially absorbed by tissue water, non-heme proteins and lipids, where preferentially absorbed wavelengths are wavelengths whose absorption is substantially independent of the individual concentrations of non-heme proteins and lipids, and is substantially dependent on the sum of the individual concentrations of non-heme proteins and water.
15. (Original) The device of claim 1, wherein said light emission optics are tuned to emit radiation at a plurality of narrow spectral wavelengths chosen to ensure that measured received



radiation are substantially insensitive to scattering variations and such that the optical path lengths through the dermis at said wavelengths are substantially equal.

16. (Original) The device of claim 1, wherein said light emission optics are tuned to emit radiation at a plurality of narrow spectral wavelengths chosen to ensure that measured received radiation from said tissue location are insensitive to temperature variations, where said wavelengths are temperature isosbestic in the water absorption spectrum or said received radiation are combined in a way that substantially cancel temperature dependencies of said individual received radiation when computing tissue water fractions.

17. (Original) The device of claim 1, wherein said light emission optics are tuned to emit radiation at a plurality of narrow spectral wavelengths chosen from one of three primary bands of wavelengths of approximately 950-1400 nm, approximately 1500-1800 nm and approximately 2000-2300 nm.

18. (Original) The device of claim 1, wherein said light emission optics and said light detection optics are mounted within said probe housing and positioned with appropriate alignment to enable detection in a transmissive mode.

19. (Original) The device of claim 1, wherein said light emission optics and said light detection optics are mounted within said probe housing and positioned with appropriate alignment to enable detection in a reflective mode.

20. (Original) The device of claim 1, wherein said light emission optics and said light detection optics are placed within a remote unit and which deliver light to and receive light from said probe housing via optical fibers.



21. (Original) The device of claim 1, wherein said light emission optics comprise at least one of a (a) incandescent light source, (b) white light source, and (c) light emitting diode ("LED").

22. (Original) The device of claim 1, wherein said processing device receives and compares at least two sets of optical measurements, where the at least first set of optical measurements corresponds to the detection of light whose absorption is primarily due to water and non-heme proteins, and where the at least second set of optical measurements corresponds to the detection of light whose absorption is primary due to water, and where a comparison of said at least two optical measurements provides a measure of a fat-free or lean water fraction within said tissue location.

23. (Original) The device of claim 1, wherein said processing device receives and compares at least two sets of optical measurements, where said at least two sets of optical measurements are based on received radiation from at least two wavelengths and which are combined to form a ratio of combinations of said received radiation.

24. (Original) The device of claim 23, wherein said processing device forms a weighted summation of said combinations.

25. (Original) The device of claim 1, wherein said processing device receives and compares at least two sets of optical measurements from at least two different wavelengths, where absorption of light at said at least two different wavelengths is primarily due to water which is in the vascular blood and in the extravascular tissue, and where a ratio of said at least two measurements provides a measure proportional to the difference between the fractions of water in the blood and surrounding tissue location.



26. The device of claim 1, wherein said water content metric,  $f_w^l$  is determined such

$$\text{that } f_w^l = \frac{\left[ \sum_{n=1}^N p_n \log\{R(\lambda_n)\} \right] - \left[ \sum_{n=1}^N p_n \right] \log\{R(\lambda_{N+1})\}}{\left[ \sum_{m=1}^M q_m \log\{R(\lambda_m)\} \right] - \left[ \sum_{m=1}^M q_m \right] \log\{R(\lambda_{M+1})\}}, \text{ and where:}$$

$p_n$  and  $q_m$  are calibration coefficients;

$R(\lambda)$  is a measure of a received radiation at a wavelength; and

$n=1-N$  and  $m=1-M$  represent indices for a plurality of wavelengths which may comprise of the same or different combinations of wavelengths.

27. (Original) The tissue water fraction as determined in claim 26, wherein  $M$  and  $N$  are both equal to 3, the wavelengths indexed by  $m$  and  $n$  comprise of the same combination of wavelengths, and said first, second, third and fourth wavelengths are approximately 1180, 1245, 1275 and 1330 nm respectively.

28. (Original) A device for measuring a body-tissue metric using optical spectrophotometry, comprising:

a probe housing configured to be placed proximal to a tissue location which is being monitored;

light emission optics connected to said housing and configured to direct radiation at said tissue location;

light detection optics connected to said housing and configured to receive radiation from said tissue location; and

a processing device configured to process radiation from said light emission optics and said light detection optics to compute said metric wherein said body tissue metric comprises a quantified measure of a ratio of a difference between the water



fraction in the blood and the water fraction in the extravascular tissue over the fractional volume concentration of hemoglobin in the blood.

29. (Original) The device of claim 28 wherein said metric is a water balance index  $Q$ , such that:

$$Q = \frac{f_w^{IV} - f_w^{EV}}{f_h^{IV}} = a_1 \frac{(\Delta R / R)_{\lambda_1}}{(\Delta R / R)_{\lambda_2}} + a_0$$

where  $f_w^{IV}$  and  $f_w^{EV}$  are the fractional volume concentrations of water in blood and tissue, respectively,  $f_h^{IV}$  is the fractional volume concentration of hemoglobin in the blood,  $(\Delta R / R)_{\lambda}$  is the fractional change in reflectance at wavelength  $\lambda$ , due to a blood volume change in the tissue, and  $a_0$  and  $a_1$  are calibration coefficients.

30. (Original) The device of claim 29 further comprising an input device configured to enable a user to input a fractional hemoglobin concentration in blood for use by said processing device.

31. (Original) The device of claim 30 wherein said processing device is further configured to compute a measure of the change in water content between the intravascular fluid volume ("IFV") and extravascular fluid volume ("EFV") using said water index.

32. (Original) The device of claim 29 wherein said first and second wavelengths are approximately 1320 nm and approximately 1160 nm respectively.

33. (Original) The device of claim 28 wherein said light emission optics are tuned to emit radiation at a plurality of narrow spectral wavelengths chosen from one of three primary bands of



wavelengths of approximately 950-1400 nm, approximately 1500-1800 nm and approximately 2000-2300 nm.

34. (Original) The device of claim 28 wherein said body-tissue metric further comprises an integral of said difference to provide a measure of the water that shifts into and out of the capillaries.

35. (Original) A method for measuring a body-tissue water content metric in a human tissue location as a fraction of the fat-free tissue content of a patient using optical spectrophotometry, comprising:

placing a probe housing proximal to said tissue location;

emitting radiation at said tissue location using light emission optics configured to direct radiation at said tissue location;

detecting radiation using light detection optics configured to receive radiation from said tissue location;

processing said radiation from said light emission optics and said light detection optics;

computing said water content metric, wherein said water content metric,  $f_w^I$  is determined

$$\text{such that } f_w^I = \frac{\left[ \sum_{n=1}^N p_n \log\{R(\lambda_n)\} \right] - \left[ \sum_{n=1}^N p_n \right] \log\{R(\lambda_{N+1})\}}{\left[ \sum_{m=1}^M q_m \log\{R(\lambda_m)\} \right] - \left[ \sum_{m=1}^M q_m \right] \log\{R(\lambda_{M+1})\}}, \text{ and where:}$$

$p_n$  and  $q_m$  are calibration coefficients;

$R(\lambda)$  is a measure of a received radiation at a wavelength;

$n=1-N$  and  $m=1-M$  represent indexes for a plurality of wavelengths which may comprise of the same or different combinations of wavelengths; and

displaying said water content metric on a display device connected to said probe housing.



36. (Original) A method for measuring a body-tissue metric in a human tissue location using optical spectrophotometry, comprising:

placing a probe housing proximal to said tissue location;  
emitting radiation using light emission optics configured to direct radiation at said tissue location;  
detecting radiation using light detection optics configured to receive radiation from said tissue location;  
processing said radiation from said light emission optics and said light detection optics to compute said metric wherein said body fluid-related metric comprises a quantified measure of a ratio of a difference between the water fraction in the blood and the water fraction in the extravascular tissue over the fractional volume concentration of hemoglobin in the blood; and  
displaying said metric or a quantity derived from said metric on a display device.

37. (Original) The method of claim 36 wherein said metric is a water balance index  $Q$ , such that:

$$Q = \frac{f_w^{IV} - f_w^{EV}}{f_h^{IV}} = a_1 \frac{(\Delta R / R)_{\lambda_1}}{(\Delta R / R)_{\lambda_2}} + a_0$$

where  $f_w^{IV}$  and  $f_w^{EV}$  are the fractional volume concentrations of water in blood and tissue, respectively,  $f_h^{IV}$  is the fractional volume concentration of hemoglobin in the blood,  $(\Delta R / R)_\lambda$  is the fractional change in reflectance at wavelength  $\lambda$ , due to a blood volume change in the tissue, and  $a_0$  and  $a_1$  are calibration coefficients.

38. (Original) A method of measuring a physiological parameter in a human tissue location, comprising:

emitting radiation at said tissue location using light emission optics configured to direct radiation at said tissue location;



detecting radiation using light detection optics configured to receive radiation from said tissue location;  
processing said radiation from said light emission optics and said light detection optics;  
and  
computing said physiological parameter, wherein said parameter is determined such that

$$\text{it is equal to } \frac{\left[ \sum_{n=1}^N p_n \log\{R(\lambda_n)\} \right] - \left[ \sum_{n=1}^N p_n \right] \log\{R(\lambda_{N+1})\}}{\left[ \sum_{m=1}^M q_m \log\{R(\lambda_m)\} \right] - \left[ \sum_{m=1}^M q_m \right] \log\{R(\lambda_{M+1})\}}, \text{ and where:}$$

$p_n$  and  $q_m$  are calibration coefficients;

$R(\lambda)$  is a measure of a received radiation at a wavelength;

$n=1-N$  and  $m=1-M$  represent indexes for a plurality of wavelengths which may comprise of the same or different combinations of wavelengths.

39. (Original) The method of claim 38, wherein said physiological parameter is the tissue water fraction in said tissue location.

40. (Withdrawn) The method of claim 38, wherein said physiological parameter is an oxygen saturation value in said tissue location.

41. (Withdrawn) The method of claim 38, wherein said physiological parameter is a fractional hemoglobin concentration in said tissue location.

42. (Withdrawn) The method of claim 38, wherein said physiological parameter is



the fractional concentration of hemoglobin in a first set comprised of one or more species of hemoglobin with respect to the concentration of hemoglobin in a second set comprised of one or more hemoglobin species in tissue.

43. (Withdrawn) The method of claim 42 wherein the coefficients,  $p_n$ , are chosen to cancel the absorbance contributions from all tissue constituents except the hemoglobin species included in set 1 and the coefficients,  $q_m$ , are chosen to cancel the absorbance contributions from all tissue constituents except the hemoglobin species included in set 2.

44–47. (Canceled)